EXHIBIT P

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES LISTED ON MOTION EXHIBIT A**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

AFFIDAVIT OF SIMON SMITH, B.Sc., MIBMS

I, Simon Smith, hereby declare:

1. I am over the age of 18.

2. I am co-founder and Chief Technical Officer for Histion, LLC ("Histion"). I earned my Bachelor of Science degree with honors in human biology from Brooke's University of Oxford (UK) and became a state registered laboratory scientist in 1989, I have been a Member of the Institute of Biomedical Scientists (IBMS) since 1990, an organization that specializes in the advanced training of laboratory scientists, and in 1991, I earned my advanced diploma (MIBMS) in Cellular Pathology from the University of Westminster, London (UK). Following my training in a clinical pathology laboratory, I worked as a research histology technician specializing in histology of osteoarticular medical devices and biomaterials for orthopedic and other applications at the University of London, Howmedica Inc. (then a division of Pfizer, Inc.), Stryker Orthopedics, Skeletech Inc., the Allen Institute for Brain Science, and since 2007, Histion, LLC. I have been performing histology, including H&E staining, on a routine basis since 1988, and have routinely

applied quality control methods and processes on histology slides (including samples stained with H&E) since becoming state registered in 1989.

3. I personally performed the specimen staining for Histion Study No. H16-008.

4. Histion is a GLP (good laboratory practices) compliant laboratory per the Code of Federal Regulations 21 CFR Part 58 and, as such, routinely generates histology sections used to generate technical data and scientific reports that are submitted to the FDA and other regulatory agencies.

5. As part of Histion's standard operating procedures (SOPs), Histion implements quality control processes and maintains quality control records for each experiment it performs. Variation in the intensity and quality of stains is a well-known aspect of preparing slides for microscopic analysis, and quality control is necessary to ensure that a slide's stain is not too light or too dark.

6. The quality control process for Histion Study No. H16-008 consisted of using rabbit skin tissue as a positive control for determining the effectiveness and quality of the H&E stain for each batch. If the rabbit skin tissue did not pass quality control, then the entire batch was rejected and a new batch of specimens were cut (using the same microtome on the same paraffin-embedded samples) or cut and ground (using the same plastic embedded samples) and stained based on the protocol, with any modifications necessary to ensure appropriate staining of the positive control tissue. Making modifications of this type to ensure adequate staining is required for appropriate assessment of histology sections, expected and widely accepted in the field of Histology.

7. I personally performed quality control assessments for Histion Study No. H16-008.

8. The original batch of resin-embedded specimens for Study No. H16-008 (Slide Nos. 16-001-24 to -46 & -48) failed quality control because, based on my professional judgment, training, and experience, the resin surrounding the rabbit tissue positive control had stained too dark as there was an unacceptable overlap in staining intensity between the rabbit tissue and the background of the slide. The reason for rejecting the first set of slides did not take into consideration the test slides (*i.e.,* slides containing Prolene specimens). The desired result for any H&E-stained section is adequately stained tissue, showing differential staining of tissue components, with either zero or minimal staining of the embedding plastic, which was achieved with the second set of stained slides, which allowed the test slides for that run to also be accepted.

9. The original batch of paraffin-embedded specimens for Study No. H16-008 (Slide Nos. 16-008-1 to -23 & -47) failed quality control because, based on my professional judgment, training, and experience, the gelatin adhesive used to enable retention of the thinly-cut mesh material on the slide was unacceptably overstained, reducing the contrast between the positive control tissue and the background of the slide. The desired result is adequately stained tissue, showing differential staining of tissue components, with zero or minimal staining of the gelatin adhesive used to retain the Prolene mesh material on the slide. This acceptable result was achieved on the second set of stained slides, which allowed the test slides for that run to pass.

10. No specimens in Study No. H16-008 failed quality control based on examination of slides containing Prolene mesh fibers.

11. As a GLP-compliant laboratory, Histion is required to keep detailed records of our processing steps as part of each experiment. This includes records of all passed and all

failed QC slides. Histion satisfied these requirements in Study No. H16-008 by recording and maintaining the details of each step of our processes.

FURTHER THE AFFIANT SAYETH NOT

Simon Smith, B.Sc., MIBMS

Sworn to and subscribed before me this
31st day of May 2016

MARGIE L. MACDONALD NOTARY PUBLIC STATE OF WASHINGTON COMMISSION EXPIRES 10-06-18

Notary Public, STATE OF WASHINGTON 5/31/16
Comm. EXP. 10/6/18